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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A23C 9/00

A2

(11) International Publication Number: **WO 00/24266**

(43) International Publication Date: 4 May 2000 (04.05.00)

(21) International Application Number: PCT/US99/22657

(22) International Filing Date: 29 September 1999 (29.09.99)

(30) Priority Data:

60/105,649	26 October 1998 (26.10.98)	US
09/255,194	22 February 1999 (22.02.99)	US

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

Without international search report and to be republished upon receipt of that report.

(54) Title: SOY AND IMMUNOGLOBULIN COMPOSITIONS

(57) Abstract

The present invention is directed to compositions including a soy product and an active immunoglobulin for nutrition and overall health benefits to humans and animals. The compositions of the invention can be in the form of a tablet, capsule, powder, liquid, functional food, beverage or special use food.

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SOY AND IMMUNOGLOBULIN COMPOSITIONS

Field of the Invention

The present invention is directed to foods and other nutritional products. More specifically, the invention provides compositions comprising soy products in combination with active immunoglobulins for nutrition and overall health benefits to humans and animals.

Background of the Invention

The nutritional benefits of soybeans have been known for centuries. Clinical studies documenting the prophylactic and therapeutic effects of whole soy beans or soy components are becoming more prevalent. Soybeans are a complete protein source containing the eight essential amino acids and are low in saturated fats, high in polyunsaturated fats and contain no cholesterol.

In addition, soy beans contain phytoestrogen compounds which are similar to estrogens. Two well known phytoestrogens are lignans and isoflavones. Isoflavones are composed primarily of three compounds: genistein, daidzein and glycitein. Isoflavones have been shown to reduce LDL cholesterol without decreasing HDL cholesterol. In addition, isoflavones can act to block estrogenic activity to slow the loss of bone density in osteoporosis and reduce some negative symptoms of menopause. Other components of soy beans which have beneficial effects include saponins, phytates, phytosterols and fatty acids.

Immunoglobulins (antibodies) are high molecular weight proteins produced by animals in response to antigenic stimulation from bacteria, viruses, fungi,

protozoa, toxins, etc. The therapeutic and preventative role of immunoglobulins in health and disease of humans and animals are well known. Raw human or animal milk is an excellent source of immunoglobulins. However, often times, milk or milk products which have been processed for human consumption using pasteurization or other treatment of the milk inactivates the immunoglobulins and destroys or significantly reduces the desired beneficial effects of the immunoglobulins. For example, milk that is available in grocery stores having a short shelf life often contains only 20-60% active immunoglobulins. Extended shelf life milk may contain as little as 0-10% of active immunoglobulins. Once inactivated, the value of the immunoglobulins is provided mainly in their availability as an amino acid source rather than for enhancing immune function.

Although the beneficial effects of soy products and immunoglobulins are known, there is a need for compositions which provide the benefits of these components and others in a form convenient for use by consumers or clinicians.

Summary of the Invention

The present invention is directed to novel compositions containing soy products and immunoglobulins which can be used for treatment or prevention of disease in humans and animals.

In general, a composition according to the invention includes an active immunoglobulin and a soy product for promoting health of a human or animal. In some embodiments, the composition includes an active immunoglobulin reactive against a selected antigen.

Generally, a composition of the invention will provide the active immunoglobulin and soy product in a ratio of about 1:1000 to 1000:1. Typically, a single serving of the composition will comprise the soy product in an amount of about 20 mg - 20 g per serving.

In some embodiments, the soy product can be a selected one or more of the group of soy products including isoflavones, soy milk, soy protein, soy phytoestrogens, etc. A composition of the invention can further include a vitamin/mineral premix, yogurt culture, fruit, fruit juice or natural or artificial flavorings for enhancing consumer acceptance or palatability.

A composition of the invention can be advantageously used for maintaining overall health of a human or animal. In some embodiments, a composition of the invention can be particularly advantageous for treating certain gastrointestinal conditions. Alternatively, a composition of the invention can be formulated as a complete meal, such as a meal replacement beverage, enteral feeding product or infant formula.

Detailed Description

The compositions and methods of the invention are formulated to provide humans or animals with a high quality nutritional source that enhances immune system function and benefits overall health. The products can be formulated for use as a dietary supplement, medical food, clinical nutrition product, functional food, dairy substitute, or a total dietary substitute for infants or for use during certain disease conditions.

The compositions of the invention include a soy product and an active immunoglobulin and will be generically referred to as an "SI" composition. The SI

compositions can be ingested or administered orally or enterally and can be provided neat in the form of a tablet, capsule, powder or liquid or in combination with additional components, set forth below, to form functional foods such as energy bars, sports or health nutrition beverages, adult nutritional supplements, dairy food supplements or special use foods such as enteral feeding products, meal replacement beverages or infant formulas.

It will be noted that in several places throughout the specification, guidance is provided through lists of examples. In each instance, the recited list serves only as a representative group. It is not meant, however, that the list is exclusive. In addition, throughout the specification, the use of the singular forms "a," "an," and "the" are to be understood to include one and more than one, unless the content clearly dictates otherwise. Thus, for example, reference to a composition containing "a soy product" includes more than one soy product. Reference to "an active immunoglobulin" includes more than one active immunoglobulin, etc.

Soy Products

As used herein, a "soy product" refers generically to soybeans and products that are produced, extracted or otherwise derived from soy beans including soy milk, tofu, soy proteins (including crude soy proteins and soy protein isolates), soy phytoestrogens such as isoflavones and lignans, soy fiber, phytic acid, trypsin inhibitors, soy globulins, etc.

In addition, certain components of soy beans, such as isoflavones are found in other plants including, for example, red clover, chickpeas, black cohosh and kudzu. Thus, it will be appreciated that in some compositions of the invention containing individual soy components, such as isoflavones, substitution of a soy

isoflavone with a synthetic isoflavone (e.g., ipriflavone) or natural isoflavone derived from plants other than soy, is within the scope of the present invention. Typically, however, the greatest benefits of an SI composition of the invention will be provided by use of the full complement of isoflavones isolated from soy beans (e.g.,. genistein, daidzein and glycitein) with or without soy proteins or other components of the soy bean. Methods for preparing soy milk, soy protein, soy phytoestrogens or other soy isolates are known and incorporated by reference herein.

Immunoglobulins

An immunoglobulin of an SI composition of the present invention is an active immunoglobulin. As used herein, an "active immunoglobulin" refers to an immunoglobulin that is capable of binding to an antigen (e.g., a toxin; allergen; pathogenic microorganism such as bacteria, viruses, fungi and protozoa; etc.) and functioning with the immune system to destroy or inactivate the antigen. Thus, unlike some products containing immunoglobulins that have been inactivated during processing, the immunoglobulins of the present invention are functional. Generally, the activity of immunoglobulins can be reduced due to exposure of raw milk, whey or other immunoglobulin source to (1) excessive thermal (time or temperature) conditions; (2) excessive bacterial activity; or (3) excessive enzymes added in processing or resulting from bacterial activity.

Examples of some typical products containing immunoglobulins whose activity has been significantly reduced or destroyed include whey protein concentrates, yogurt, certain heat or chemically pasteurized milks, non-fat dry milk, etc.

The level of activity of immunoglobulins suitable for a composition of the invention can be determined using radial immunodiffusion assay detection (RID) or enzyme linked immunosorbant assays (ELISA) against antigens that are ubiquitous in the environment of a human or animal from which the immunoglobulins are obtained. For cattle, such ubiquitous immunoglobulins include *Escherichia coli* strain K-99, rotavirus, *Cryptosporidium parvum*, etc. An active immunoglobulin of the invention can be provided in a liquid or powdered form, including lyophilized or spray dried powders. The active immunoglobulins generally have an activity that is at least 50%, generally greater than 75%, typically greater than 85%, preferably greater than 90% of the activity of the raw immunoglobulin present in the immunoglobulin source prior to any processing.

As will be discussed below, in some embodiments, the SI composition can contain active immunoglobulins having enhanced activity against a selected antigen resulting from immunization of a human or animal, from which the immunoglobulins are collected, against the selected antigen.

An active immunoglobulin according to the invention can be derived from any known source of immunoglobulins including milk, skim milk, colostrum, skim colostrum, whey, blood, monoclonal or polyclonal antibody producing cell culture, saliva, etc. Typically, the immunoglobulins can be collected from a mammal, including human, sheep, goat, cattle, buffalo, water buffalo, yak, horse, pig, llama, rabbit, mouse, etc. A particularly advantageous source of active immunoglobulins is bovine colostrum or milk.

Methods are known for preparing active immunoglobulins. The active immunoglobulins can be isolated from the immunoglobulin source. Alternatively,

the active immunoglobulins can include one or more bioactive components typically associated with the immunoglobulins when in the source. Examples of bioactive components associated with immunoglobulins in milk include lactoferrin, lactoperoxidase, growth factors, cytokines, etc. One example of a preferred active immunoglobulin product including other bioactive components is Proventra®, which is commercially available from Galagen, Inc, Arden Hills, MN, the assignee of the present invention. Proventra® provides active immunoglobulins in combination with natural immune components such as lactoferrin, lactoperoxidases, growth factors, cytokines, etc.

Processes for preparing active immunoglobulins are disclosed in, for example, U.S. Patent Nos. 5,531,988, 5,531,989, 4,834,975 and 4,816,252, the disclosures of each being incorporated herein by reference. Preferred processes for preparation of active immunoglobulins suitable for the invention are disclosed in U.S. Patent No. 5,707,678, the entire disclosure of which is incorporated herein by reference.

Because immunoglobulins can be denatured by high temperatures, low pH, or a combination of these conditions, careful monitoring and control of temperature and pH levels is important in processes for purification of active antibodies from a source. The following preferred process for preparing a protein concentrate containing active immunoglobulins also utilizes microfiltration to reduce the bioburden associated with the protein concentrate. The process conditions, including temperature and pH of the product, is preferably controlled during purification to maximize the efficiency of the described microfiltration process and avoid denaturation of immunoglobulins.

This method for microfiltration of milk, milk serum, colostrum or colostral serum is carried out using milk, milk serum, colostrum or colostral serum from a mammal as the immunoglobulin source. As described above, the mammal may be immunized or hyperimmunized against a selected antigen. Colostrum collected during the first three days after parturition is especially preferred. The milk, milk serum, colostrum or colostral serum may be frozen until sufficient quantities are collected to produce the desired amount of immunoglobulin fortified protein concentrate.

If the immunoglobulin source is frozen, care should be taken that the heat applied to thaw the frozen milk, milk serum, colostrum or colostral serum does not cause immunoglobulin denaturation. The temperature is controlled to reduce the risk of heat denaturation while thawing. Preferably, the temperature used to thaw the frozen milk, milk serum, colostrum or colostral serum should be no more than about 130°F (54°C). The final temperature of the thawed starting material is preferably about 110°F (43°C).

Cream or fat is separated from the milk, milk serum, colostrum, or colostral serum by centrifugation. After the initial separation, the fat may be resuspended and separated a second time to recover as much of the skim as possible. Temperature is not critical at this step, so long as there is no risk of immunoglobulin denaturation. A temperature range of about 75° to 110°F (24° to 42°C) is desirable.

Next the defatted milk, milk serum, colostrum or colostral serum is acidified to precipitate casein. This can be done by lowering the pH from about 6.0 to about 4.5 to 5.0, preferably about 4.5 to 4.7. Any acid can be used to lower the pH of the product, such as hydrochloric, phosphoric, lactic, etc., with lactic acid being

preferred. To avoid the development of localized low pH areas which lead to immunoglobulin denaturation, the acid delivery rate should be fairly slow. Preferably, the acid delivery rate should be such that the pH is lowered by about 0.2 units every five minutes. After casein is precipitated it is removed, preferably by centrifugation, to give whey.

The whey obtained after removal of the fat and casein may be immediately microfiltered if desired. Alternatively, an ultrafiltration step can be performed to remove lactose minerals such as calcium from the whey and concentrate the proteins in the whey. This ultrafiltration, performed at an acidic pH, ensures that the protein concentrate can consistently be microfiltered without fouling or clogging of the microfilter. This initial ultrafiltration substantially reduces the concentration of calcium found in the resulting protein concentrate and prevents microfilter clogging or fouling associated with the presence of calcium phosphate or other calcium complexes.

A preparatory ultrafiltration step can be carried out at a pH that is sufficiently low to maintain the calcium in its soluble ionic form and prevent formation of calcium phosphate or other complexes, but not so low as to denature or damage immunoglobulins, proteins or other desirable substances. In general, maintaining pH at a level of about 4.5 to 5.0 will maintain calcium solubility but not denature immunoglobulins or otherwise reduce immunoglobulin levels.

The ultrafiltration can be carried out at a wide range of temperatures. Although elevated temperatures can encourage precipitation of calcium complexes such as calcium phosphate, maintaining pH at the above recited levels reduces this tendency so that the ultrafiltration can be carried out even if the material is warm.

Slightly warmer temperatures can also increase the flux rate observed during ultrafiltration. Typically, the ultrafiltration is carried out at a temperature ranging from about 4° to 50°C, preferably about 20° to 40°C.

Ultrafiltration of the acidified material may be performed using any of the ultrafilter housings and membranes known in the art. Ultrafilter membranes having a molecular weight cutoff of about 3,000 to 100,000 can be used to provide a consistently microfilterable protein concentrate. Preferably the ultrafilter membrane has a molecular weight cutoff of bout 3,000 to 30,000. Suitable housings and membranes are available commercially, such as the S10Y30 and S40Y30, available from Amicon, Inc., Beverly, MA, and the S2-HFM-100-VYV available from Koch Membrane Systems, Wilmington, MA.

In a preferred embodiment, diafiltration is carried out at some point during the ultrafiltration. The diafiltration may be performed using known techniques, such as constant volume diafiltration or batch diafiltration. Diafiltration allows for the calcium concentration of the protein concentration to be substantially reduced. "Substantial reduction" of calcium levels is a term used to indicate that the total calcium present in the ultrafilter concentrate (the protein concentrate) is about 1 to 10 percent of the amount present in the ultrafilter feed (the protein concentrate). Reduction of calcium levels reduces the risk of clogging or fouling during later microfiltration or heat exchange operations and may be desirable for other reasons, such as production of a protein product having reduced mineral content. Preferably, the calcium concentration in the ultrafilter concentrate is about 30 to 60 percent in the level found in the ultrafilter feed.

The protein concentrate, processed by the above method, can be consistently microfiltered without the microfilter becoming clogged or fouled. If desired, the pH of the protein concentrate can be adjusted to about 6.0 to 7.0 before microfiltration.

Preferably, the product can be maintained at the acidified pH of about 4.5 to 5.0, preferably about 4.5 to 4.7 through the microfiltration step to minimize bacterial growth. This microfiltration reduces the bioburden in the product by at least about 4 logs. If further microfiltration is desired, this step allows for easier and more efficient microfiltration.

In a preferred embodiment, the microfilter is operated at a constant feed rate until the maximum transfilter pressure differential of about 40 psi is reached. This transfilter pressure differential is maintained by reducing the filter feed rate to prevent contaminant breakthrough.

After the microfiltration is complete the product, which has a substantially reduced bioburden content and active immunoglobulin levels of about 95-100% relative to the starting material, can be further processed. For example, the immunoglobulins may be further concentrated or purified using methods known in the art.

According to the invention, active immunoglobulins can be provided in an SI composition in the form of powdered or liquid bovine immunoglobulin concentrate (BIC). Alternatively, active immunoglobulins can be in a powdered or liquid form such as pasteurized defatted bovine colostrum (PDBC), whey protein isolates, etc.

In some embodiments, the active immunoglobulins can be collected from a human or animal that has been specifically immunized against selected antigenic targets. Examples of antigenic targets against which specific immunoglobulins may

be prepared include bacteria (*Escherichia, coli*, *Campylobacter jejuni*, *Helicobacter pylori*, *Clostridium difficile*, *Salmonella* spp., *Shigella* spp., *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus* spp., *Mycobacterium* spp., *Pseudomonas aeruginosa*, *Prevotella*, *Actinomyces*, etc.), yeast (*Candida albicans*, *Candida* spp., *Cryptococcus neoformans*, *Zygomycetes*), viruses (rotavirus, influenza virus, herpes virus), protozoa (*Cryptosporidium parvum*, *Giardia lamblia*, *Isospora belli*, *Microsporidium*), toxins (*C. difficile* toxins A and B, cholera toxin, Shiga-like toxins, heat-labile toxins), purified colonization factors, adhesins, pili antigens, etc.

Additional Components

An SI composition according to the invention can include additional components to fortify the nutritional or therapeutic benefit of the composition or enhance consumer acceptance through natural or artificial flavoring or coloring.

In some embodiments, an SI composition can include yogurt cultures or kefir cultures to replenish or enhance normal gastrointestinal flora. Bacterial organisms suitable for yogurt culture include, for example, bacteria of the Lactobacillus and Bifidobacterium genera, such as, *L. acidophilus, L. bulgaricus, L. casei, L. fermentum, L. salivaroes, L. brevis, L. leichmanii, L. plantarum, L. cellobiosus, B. infantis, B. longum, B. thermophilum and B. bifidum*. Other bacterial organisms include *Streptococcus thermophilus*.

Kefir cultures are a known fermented milk product containing a mixture of symbiotic yeast, lactobacilli, leuconostocs and lactic streptococci.

Vitamins and minerals can also be added to enhance the nutritional benefits provided by an SI of the invention. Vitamins include fat soluble and water soluble vitamins and minerals include macro and micro minerals.

In addition, natural fruits, fruit juices or fruit seeds can be included for flavor, texture and added nutritional benefit. Suitable fruits and fruit seeds include, for example, banana, pineapple, apple, orange, peach, strawberry, cherry, raspberry, blueberry, kiwi, nuts, rice, etc.

In addition, artificial flavoring and colors can be added to enhance and accommodate consumer acceptance and preferences. FDA approved artificial flavorings and colorings for use in food products are known and suitable for an SI composition of the invention.

Soy product and Immunoglobulin Compositions

A soy product and immunoglobulin composition according to the invention comprises a mixture of a soy product and an active immunoglobulin. A single "serving" of the SI composition can be in the form of a tablet, capsule or powder, liquid, that can be ingested alone or added to water, juice, milk, ice cream, yogurt, etc. by the consumer prior to ingestion. Alternatively, the SI can be provided in a single or multiple serving form of a functional food or nutraceutical, such as a sports or health nutrition beverage, adult nutritional supplement or energy bar. In another embodiment, the SI composition can be a dairy food substitute such as an active immunoglobulin fortified soy milk, soy yogurt, soy yogurt beverage, or frozen SI dessert products. An SI composition can also be prepared as a special use food, in combination with other nutrients, to provide a fully balanced meal to be used, for example, as a meal replacement beverage, enteral feeding product or infant formula.

In a typical embodiment, the active immunoglobulins of a serving of an SI composition can be present in an amount of about 20 mg to 20 g dry weight of active immunoglobulin. The soy product can be any form including soy proteins,

isoflavones, crude soy extract including isoflavones and soy proteins, etc. in an amount of about 20 mg - 20 g of soy product per serving. The SI composition can be present in a ratio of active immunoglobulin to soy product of about 1:1000-1000:1, generally about 1:750 to 750:1, typically about 1:500 to 500:1.

In one embodiment, an SI composition can provide a soy milk product having similar or greater benefit than cows milk due to the increased levels of active immunoglobulins and associated immune enhancing factors. Use of products according to the invention may be in the medical nutrition area (administered under a physicians guidance), dietary supplement arena, or as typical consumer products that may be formulated as fresh or frozen products, shelf-stable products, powders, capsules, tablets, etc.

Methods for preparing tablets and capsules are known. Tablets can be prepared by combining an SI composition with conventional excipients, binders and disintegrants, including, for example, polyvinyl pyrrolidone, sodium citrate, calcium carbonate and dicalcium phosphate, starch, alginic acid, complex silicates, milk sugar, gelatin, acadia, etc. Additionally, lubricating agents such as magnesium stearate, sodium laurel sulfate and talc are often very useful for tableting purposes. SI compositions may also be formulated into oral gelatin capsules, including excipients such as, lactose or milk sugar, as well as high molecular weight polyethylene glycols, etc.

In some embodiments, an SI composition can be prepared with immunoglobulins active against specific antigens. According to this embodiment, the ratio of soy product to active immunoglobulin will be the same as described

above for soy products combined with broad spectrum active immunoglobulin products.

In addition, while the present specification describes an SI composition for use in humans, it will be appreciated that the nutritional and therapeutic benefits of an SI composition will be equally suited for use in animals, for nutritional as well as therapeutic purposes.

The following Examples are provided to further describe products containing SI compositions according to the invention. The Examples, however, are not intended to limit the scope of products which can be prepared within the spirit and scope of the invention.

Examples

Example 1 Immunoglobulin Fortified Soy Milk

8 oz (240 ml) of soy milk is combined with 50-100 mg of dry active immunoglobulins. This composition provides a milk substitute product having the approximate active immunoglobulin content of pasteurized whole milk. Combining 8 oz. (240 ml.) of soy milk with 200-1500 mg of dry active immunoglobulins provides a milk substitute product having the approximate active immunoglobulin content of unpasteurized raw milk.

Example 2 Immunoglobulin Fortified Soy Yogurt

6 oz. of soy yogurt prepared by adding an active culture of *L. acidophilus* or other suitable bacterial culture is combined with 20-50 mg of dry active immunoglobulins. 0.05% of the total product weight of a known vitamin/mineral

premix can be added. The active yogurt cultures can be added in an amount of about 0.05% of the total product weight.

Example 3 Health/Energy Bar

4-5% of soy yogurt solids are combined with approximately 70-75% of a fruit base selected from one or more of banana, strawberry, raspberry, apple, blueberry, peach, etc., to prepare a bar An active immunoglobulin is added in an amount of about 1-10% dry weight of the total bar weight. According to one embodiment, an additional 8-12 % of the total bar weight can include nuts or rice. A known vitamin/mineral premix can be included in an amount of about 4% of the total bar weight. Artificial flavoring and natural or artificial coloring can also be added.

Example 4 High Protein Beverage

For a high protein beverage, 10 g of soy protein isolates and 50-500 mg of dry active immunoglobulins can be added to 240 ml of fruit juice. 0.05-0.5% of total beverage weight of a known vitamin/mineral premix can also be added.

Example 5 Isoflavone Enhanced Immunoglobulin Supplement (Capsules or Tablets)

50-500 mg of active immunoglobulins in the form of powdered colostrum are combined with 50-1000 mg of soy protein isolates. Suitable binders, excipients and disintegrants can be added to form the capsules or tablets. As described above, methods for forming capsules and tablets known in the art and are suitable for capsules and tablets of the invention.

Example 6 Yogurt or Kefir Beverage Supplemented with immunoglobulins and Soy Protein Isolates

A yogurt or Kefir fortified beverage can be prepared by combining 1 quart of milk with 10^6-10^9 organisms of kefir or yogurt starter cultures. Organisms suitable include bacteria from the Lactobacillus and Bifidobacterium genera. 100-1000 mg dry active immunoglobulins and 2-5 grams of purified isoflavones are also added.

From the foregoing detailed description and examples, it will be evident that modifications and variations can be made in the compositions and methods of the invention without departing from the spirit or scope of the invention. Therefore, it is intended that all modifications and variations not departing from the spirit of the invention come within the scope of the claims and their equivalents.

WE CLAIM:

1 A composition for promoting health comprising:

- an active immunoglobulin ; and
- a soy product.

2. The composition according to claim 1 wherein the active immunoglobulin and soy product are present in a ratio of active immunoglobulin to soy product of about 1:1000 to 1000:1.

3. The composition according to claim 1 wherein one serving of the composition comprises the soy product present in an amount of 20 mg - 20 g per serving.

4. The composition according to claim 1 wherein the active immunoglobulin composition comprises immunoglobulins reactive with an antigen selected from the group consisting of: bacteria (*Escherichia coli*, *Campylobacter jejuni*, *Helicobacter pylori*, *Clostridium difficile*, *Salmonella* spp., *Shigella* spp., *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus* spp., *Mycobacterium* spp., *Pseudomonas aeruginosa*, *Prevotella*, *Actinomyces*, etc.), yeast (*Candida albicans*, *Candida* spp., *Cryptococcus neoformans*, *Zygomycetes*), viruses (rotavirus, influenza virus, herpes virus), protozoa (*Cryptosporidium parvum*, *Giardia lamblia*, *Isospora belli*, *Microsporidium*), toxins (*c. difficile* toxins A and B, cholera toxin, Shiga-like

toxins, heat-labile toxins), purified colonization factors, adhesins and pili antigens.

5. The composition according to claim 1 wherein the soy product is an isoflavone.

6. The composition according to claim 1 wherein the soy product is soy milk.

7. The composition according to claim 1 wherein the soy product is a soy protein.

8. The composition according to claim 6 wherein the isoflavone is genistein.

9. The composition according to claim 1 further comprising a vitamin/mineral premix.

10. The composition according to claim 1 further comprising active yogurt cultures.

11. The composition according to claim 1 further comprising fruit.

12. The composition according to claim 9 further comprising artificial colors.

13. A composition for treating a gastrointestinal composition caused by a selected antigen, the composition comprising:

- an active immunoglobulin reactive with the selected antigen; and
- a soy product.

14. The composition according to claim 13 wherein the selected antigen is selected from the group consisting of: bacteria (*Escherichia coli*, *Campylobacter jejuni*, *Helicobacter pylori*, *Clostridium difficile*, *Salmonella* spp., *Shigella* spp., *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus* spp., *Mycobacterium* spp., *Pseudomonas aeruginosa*, *Prevotella*, *Actinomyces*, etc.), yeast (*Candida albicans*, *Candida* spp., *Cryptococcus neoformans*, *Zygomycetes*), viruses (rotavirus, influenza virus, herpes virus), protozoa (*Cryptosporidium parvum*, *Giardia lamblia*, *Isospora belli*, *Microsporidium*), toxins (*c. difficile* toxins A and B, cholera toxin, Shiga-like toxins, heat-labile toxins), purified colonization factors, adhesins and pili antigens.

15. A method for treating a gastrointestinal condition caused by a selected antigen comprising:

- administering a composition comprising:
    i. an active immunoglobulin reactive with the selected antigen; and
    ii. a soy product.

16. The method according to claim 15 wherein the gastrointestinal condition treated is in a human.